REMARKS

In view of the following remarks, the Examiner is requested to reconsider and allow Claims 1 -34, the only claims pending and under examination in this application.

The Examiner is thanked for the helpful interview held on April 16, 2007 with the undersigned and Dr. Bradley Galer. During the interview, the pathophysiological differences between Carpal Tunnel Syndrome and musculoskeletal disorders and also the differences in their pain etiologies was reviewed once again, as has been submitted in prior Responses and Declarations. Furthermore, the contrasting mechanisms of action between the use of topical NSAIDS to treat musculoskeletal disorders, such as arthritis, versus when topical NSAIDS are used to treat the neuropathic symptoms of Carpal Tunnel Syndrome, were discussed The Examiner suggested that the Applicants submit a further declaration clarifying these points, which the Applicants have done and include with the present response.

CLAIM REJECTIONS – 35 U.S.C. §103

Claims 1 – 18 and 24 – 33 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921).

In maintaining this rejection, the Examiner has found the recently filed Declaration by Dr. Bradley Galer non-persuasive because:

> something that has been a source of contention in the prosecution of this case. Specifically, even though the prior art teaches that the methods and compositions disclosed therein are useful for treating pain, the question is raised of whether or not pain of a different pathology constitutes an entirely different type of condition such that those prior art methods and compositions would not have a reasonable expectation of success in treating the those types of pain of differing pathologies. In the view of the examiner, there would be a reasonable expectation of such success, which will be further explained below.

and

> A primary issue that remains unresolved in this case is whether or not pain of a different pathology constitutes an entirely different type of condition such that those prior art methods and compositions would not have a reasonable expectation of success in treating the those types of pain of differing pathologies. Given that the prior art already discloses the topical administration of non-steroidal anti-inflammatory drugs for the treatment of pain where the drug is to be administered at a location proximal to the site of pain, and further that the pharmacological action of the drug on the patient is presumably not any different between prior art methods and the instantly claimed methods, then it is the position of the examiner that no patentable distinction has been shown between types of pain that differ in their particular pathologies. Therefore, the claims remain rejected over the prior art.

As such, the Examiner still believes, despite the previously filed Declarations, that one would have a reasonable expectation of success in practicing the claimed methods because:

1) Carpal Tunnel Syndrome and musculoskeletal disorders are sufficiently similar pathologies; and

2) The mechanism of action of the NSAID in each application is presumably the same.

However, as reviewed during the personal interview held with the Examiner on April 16, 2007 and evidenced by the enclosed declaration by Dr. Bradley Galer, in fact:

1) Carpal Tunnel Syndrome and musculoskeletal disorders **are entirely distinct pathologies**; and

2) The mechanism of action of the NSAID in each application is **entirely different**.

As such, one of skill in the art would not have a reasonable expectation of success in practicing the claimed invention in view of the references cited by the Examiner. Because the combined teaching of the cited references fails to teach or suggest all of the elements of the claimed invention and fails to provide one of skill in the art with a reasonable expectation of success in the claimed methods, as reviewed above, Claims 1 – 18 and 24 -33 are not obvious under 35 U.S.C. §103(a) over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921) and this rejection may be withdrawn.

The rejection of Claims 19-23 under 35 U.S.C. §103(a) as allegedly being unpatentable over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921) and further in view of Shudo has been maintained. As demonstrated above, Petrus, Edwards and Biedermann do not teach or suggest every limitation of or provide a reasonable expectation of success in the claimed invention. As Shudo was cited for its disclosure of kits containing topical patch formulations and instructions, it fails to remedy the defects of Petrus, Edwards and Biedermann, and therefore a prima facie case of obviousness has not been established with respect to Claims 19 – 23. Accordingly, the Applicants respectfully request the Examiner reconsider and withdraw this rejection.

Finally, newly presented Claim 34 has been rejected as being obvious under 35 U.S.C. §103(a) over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559)

and Biedermann, et al. (USPN 5,980,921). For at least the same reasons provided above with respect to Claims 1-18 and 24-33, this rejection may be withdrawn.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CALD-005.

Respectfully submitted,
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Date: May 9, 2007

By: _____
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enc:

- Declaration by Dr. Bradley Galer

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